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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CHRISTOPHER J. KULISH, ESQ HOLLAND & HART LLP P. O. BOX 8749 DENVER, CO 80201-8749			EXAMINER KAROL, JODY LYNN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,427

Applicant(s)

ROGERS, LARRY D

Examiner

Jody L. Karol

Art Unit

4133

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/25/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☒ Claim(s) 24-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/25/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/US03/32267 International Filing Date: 10/10/2003, which claims priority to US Provisional Application No. 60/417593. Claims 1-26 are pending and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 3/25/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

Priority

2. Acknowledgment is made of applicant's claim for domestic priority based on the US Provisional Application No. 60/417593 filed on 10/10/2002.

Claim Objections

3. Claims 24-25 are objected to because of the following informalities: Claims 24-25 specify weight percentages for components in the soluble compound, but do not indicate what the weights are based on (i.e. the total weight of the soluble compound). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

5. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1-2 and 6-16 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Claims 3-5 and 17-26 are rejected for being dependent on a rejected base claim.

The instant claims are directed to methods for treating an environment contaminated with an undesired biological agent by applying a treatment substance to the environment that is capable of providing a crystal that can penetrate the cell wall of an undesired biological agent.

However, the specification only exemplifies silicates that are capable of providing crystals (see page 2 and 4, in particular), whereas the claims recite the treatment substances broadly. Moreover, the specification has not provided sufficient written description of a representative number of species by actual reduction to practice, reduction to drawing, or by disclosure of relevant identifying characteristics, i.e., structure or other physical or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by combination of such identifying characteristics, sufficient to show the applicant was in possession of the broadly recited claimed

genus of the treatment substances that are capable of providing a crystal that can penetrate the cell of an undesirable biological agent.

See also the below discussion on the art recognized problems regarding crystals that can penetrate the cell wall of the undesirable biological agents in the Enablement Rejection.

Enablement Rejection

6. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and used the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

- (1) The nature of the invention;
- (2) The breadth of the claims;
- (3) The relative skill of those of ordinary skill in the art;

- (4) The predictability or unpredictability of the art;
- (5) The state of the prior;
- (6) The amount of direction or guidance presented;
- (7) The presence or absence of working examples; and
- (8) The quantity of experimentation necessary to make or use the invention based on the content of the disclosure.

(1) Nature of the Invention: The instant invention pertains to a method of treating an environment that may be or is known to be contaminated with an undesirable biological agent comprising identifying the environment that may be or is contaminated, providing a treatment substance, and applying the treatment substance to the environment. The specification defines undesirable biological agents as bacteria, viruses, or spores (see page 1). The treatment substance is a substance that is capable of providing a crystal that can penetrate the cell wall of an undesirable biological agent.

(2) Breadth of the Claims: The instant claims are very broad and encompass methods for treating any environment that is contaminated or is suspected to be contaminated with any bacteria, virus, or spore. The environment is treated by applying any substance that is capable of providing a crystal that can penetrate the cell wall of the bacteria, virus, or spore.

(3) Relative Skill in the Art: The relative skill of those in the art is typically very high, i.e. experienced scientists having advanced professional degrees in the chemical and biochemical fields.

(4) State of the Prior Art: The prior art is well established for substances that are capable of providing crystals but silent on the ability of the crystals to penetrate a cell wall of a biological agent by a mechanical mechanism (i.e. puncturing, ripping, tearing, etc). Furthermore, it is known in the art that silicate crystals may bind to the cell wall of bacteria, such as the gram positive bacterium *Bacillus subtilis* in laboratory simulated soil settings, without penetrating the cell wall (see Mera et al., "Mechanism of Silicate Binding to the Bacterial Cell Wall in *Bacillus subtilis*," *J. Bacteriol.* (1993) Vol. 175, No. 7, pgs 1936-1945).

It is also well-established in the art that certain undesirable biological agents, such as bacterial spores, are resistant to a wide-variety of treatments such as heat and chemical treatment, and therefore a very difficult to kill (see Rogers et al., "Decontamination assessment of *Bacillus anthracis*, *Bacillus subtilis*, and *Geobacillus stearothermophilus* spores on indoor surfaces using a hydrogen peroxide gas generator," *Journal of Applied Microbiology*. 2005, **99**, 739-748). For example, the *Bacillus anthracis* spore, the form of bacterium that causes anthrax infection, is long lived and difficult to destroy. Noxious chemicals such as bleach, aqueous chlorine dioxide, and paraformaldehyde have typically been used in the surface treatment and fumigation of contaminated environments (see Canter, D. A., "Remediating anthrax-contaminated sites: Learning from the past to protect the future," *Chemical Health & Safety*, July/August 2005, pgs. 13-19). Another bacterial spore known to be resistant to treatment is *Clostridium difficile*. The spores are resistant to common types of and levels of general hard surface disinfectants, and oxidative microbicides, such as acidified bleach, are

necessary to rid environmental surfaces of these spores under ambient conditions without excessive contact times (see Perez et al., "Activity of selected oxidizing microbicides against the spores of *Clostridium difficile*: Relevance to environmental control," *Am. J. Infect. Control*, 2005 Aug; 33 (6):320-325).

(5) Predictability or lack thereof in the art: As the prior art does not establish that crystals are capable of penetrating the cell wall of a biological agent, there is a lack of predictability in the art as to which crystals if any, are capable of performing such function. Furthermore, the cell walls of different biological agents have different resistances to mechanical stress based on the general nature and thickness of the cell wall. For example, gram positive bacteria have a relatively thick cell wall, while gram negative bacteria have a significantly thinner cell wall. A crystal that can penetrate the cell wall of a gram negative bacterium would not necessarily be able to penetrate the thicker cell wall of a gram positive bacterium. It is also noted that viruses do not have a cell wall in the traditional sense, but are encapsulated by a layer of proteins called a capsid.

(6) Direction or Guidance Provided: The specification does not provide any direction or guidance on how to make the crystals of the treatment substance penetrate the cell wall. The specification merely suggests that a treatment substance is applied to the environment that may or may not be contaminated with the undesired biological agent, and that once applied, the crystals penetrate the cell walls of the undesired biological agent, but does not teach how one of

ordinary skill in the art would go about determining the proper parameters or additional steps necessary to invoke crystal penetration of a cell wall.

The amount of guidance or instruction necessary is inversely proportional to the level of predictability of the art. A limited number of embodiments may provide broad enablement in mechanical or electrical cases involving predictable art, however chemical and physiological arts are less predictable and require guidance that is more extensive. See *In Re Fischer*, 427 F. 2d 839, 166 USPQ 24 and *Ex Parte Hitzeman*, 9 USPQ 2d 1823.

(7) Working Examples: The specification gives no working examples and does not illustrate the specifics on how the claimed method is carried out, or the results that are obtained. The only examples found in the specification are drawn to treatment substance compositions comprising silicates as the substance capable of forming a crystal.

(8) Quantity of Experimentation Necessary: As the specification does not provide adequate guidance to one skilled in the art to readily determine how to successfully carry out the claimed method as shown by the analysis of the undue experimentation factors discussed above, one skilled in the art would have to engage in **undue experimentation** to make and use the claimed invention to its full breadth. In particular, the crystals for penetrating the cell wall of a biological agent are not fully disclosed or known. Moreover, one skilled in the art would not expect the solely exemplified treatment substance, silicates crystals, to penetrate the cell wall of the gram positive bacterium for the reasons as taught by Mera et al., *supra*.

The test for undue experimentation is not merely quantitative, since a considerable amount of routine experimentation is permissible. In the instant case, absent adequate guidance, an impermissible burden of undue and painstaking experimentation is necessary to identify and make the crystals that are capable of penetrating the cell wall of an undesirable biological agent and determine which biological agents they are effective in treating. *Genetech*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for a search, but compensation for a successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not vague intimations of general ideas that may or may not be workable."

For the above reasons and analysis of the undue experimentation factors, a person skilled in the art would have to engage in **undue experimentation** to practice the methods of the instant claims with no assurance of success.

Second Paragraph Rejection

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8, and 13-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 8 are unclear with respect to the metes and bounds of "a soap" (claim 6) or "a sodium surfactant salt" (claim 8), when the claims are read

in light of the specification. The specification discloses compounds when in contact with water produce a soap. See para [0005] of the instant PG-Pub US 2006/0034948, for instance. Moreover, the specification discloses that a soap is a "sodium surfactant salt" (see para [0013] of the instant PG-Pub). The specification also indicates that the dry compounds that exhibit the "soap" characteristics with the silicate crystal comprise sodium metasilicate, sodium carbonate, and sodium sulfate (see para [0014]). Thus, it is unclear from the claims, if the applicants are intending the inclusion of commonly known soap or surfactants, i.e. detergents or fatty acid salts, etc., or the components that are precursors of soap by the recited "soap" and "surfactant."

Claims 13-26 are unclear with respect to the recitation of "mixing said soluble compound with water to produce a slurry" in claims 13 and 17. The term "slurry" is broadly defined as a watery mixture or suspension of insoluble material (see Webster's Third New International Dictionary, Unabridged, Copyright © 1993 Merriam-Webster, Inc.; online entry for slurry). Thus, it is unclear from the claims how a soluble compound is used in the production of said slurry since a soluble compound would dissolve in water. Claims 14-16 and 18-26 are rejected for being dependent on a rejected base claim. For examination purposes, and in the interest of compact prosecution, the treatment substances of claims 13-26 are interpreted as containing the claimed soluble compound mixed with water wherein either part of the soluble compound is not dissolved or another component is present to produce said slurry.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Koper et al. (US 6,057,488).

Claim 1 is directed to a method for treating an environment that may be or is known to be contaminated with an undesirable biological agent (i.e. bacteria, virus, or spore) comprising identifying the potentially contaminated environment, providing a treatment substance, and applying the treatment substance to the environment. The treatment substance is capable of providing a crystal that can penetrate the cell wall of the undesirable biological agent. Claim 2 specifies that the treatment substance comprising a substance capable of providing a nano-crystal.

Koper et al. teaches a method for destroying a target component, such as bacteria, by contacting the target component with metal oxide adsorbent particles or mixtures thereof at the site of contamination (see abstract and column 2, lines 32). The metal oxide adsorbent particles are also referred to as crystallites, wherein the crystals are nanoscale, with an average size of up to 20 nm (see column 2, lines 41-42 and 62-64). The metal oxide particles are also specifically

referred as nanocrystals in the treatment of *Bacillus globigii* (see Example 3 at columns 9-10, and in particular column 10, lines 31-35).

Koper et al. is silent on the mechanism of action of the metal oxide particles on the destruction of target component such as bacteria. However, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 201 USPQ 658 (CCPA 1979). In the instant case, Koper et al. teaches the claimed method steps, and therefore, anticipates the instant claims 1-2.

9. Claims 1, 3-5, 7, 9, 13, 15-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Donovan et al. (US 5,480,643).

Claim 1 is described above. Claims 3-5, 7, and 9 further specify that the treatment substance comprises a silicate, a soluble silicate, a sodium metasilicate, a sodium compound, and a slurry respectively. Claim 13 is directed to a method as in claim 1, except instead of a treatment substance, a soluble compound is provided that is mixed with water to produce a slurry that is applied to the environment, and said slurry is capable of providing a crystal that can penetrate the cell wall of the undesirable biological agent. Claim 15 further specifies that the environment is identified before a soluble compound for treating the environment is provided while claim 16 specifies that the soluble compound is provided before the environment is identified. Claim 17, 18, and 23 specify

that the soluble compound is comprised of silicate, sodium metasilicate, and sodium carbonate respectively. Claims 19-20 specify that the soluble compound is comprised of disodium trioxosilicate pentahydrate and disodium trioxosilicate anhydrate respectively. Disodium trioxosilicate is synonymous with sodium metasilicate, therefore claims 19-20 are directed to hydrated and anhydrous forms of sodium metasilicate.

Donovan et al. teaches methods for treating an environment that may be or is known to be contaminated with an undesirable biological agent comprising taking action to identify the environment that may be or is known to be contaminated with the undesirable biological agents, such as identifying a biological spill, or contaminated surface or area (see abstract, etc.); providing a treatment substance for the environment, such as the solid antimicrobial composition containing absorbing agents including alkali metal silicates such as anhydrous sodium metasilicate and hydrated metasilicates (see columns 8-10, Absorbing Agent , in particular column 9, lines 39-40; Example 20 at columns 19-20, in particular column 19, lines 54 and Table XI at column 20; Example 21, column 20, line 39 for the use of Hubersorb 600 (a sodium silicate); claims 1 and 5, etc.); and applying the treatment substance to the environment such as sprinkling the composition over biological spills (see column 13, lines 31-46).

Donovan et al. also teaches that moisture adsorbent antimicrobial composition comprising an absorbent such as a silicate will absorb water quickly when applied to an aqueous spill site (see column 10, lines 55-61). This would appear to inherently meet the claimed limitation for the treatment substance

comprising a slurry (instant claim 9), and the mixing of a soluble compound with water to produce a slurry (instant claim 17), since the composition of Donovan et al. must be mixed with water (through absorption of water from the aqueous spills) in order to be activated as an antimicrobial agent (see column 3, lines 45-67).

Donovan et al. also teaches the use of buffering agents such as sodium carbonate in the particulate mixture containing silica as claimed in the instant claim 23 (see claims 7 and 11).

Donovan et al. is silent with respect to the capability of the treatment substance such as the solid antimicrobial composition comprising a silicate to provide a crystal that can penetrate the cell wall of the undesirable biological agent. However, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Furthermore, the method taught by Donovan et al. has the requisite environment, the method steps, and the treatment substance containing a silicate of the instantly claimed invention, wherein the undesirable biological are taught to be killed or neutralized. Moreover, absorbents such as silicates in the solid antimicrobial composition of Donovan et al. are the same compounds identified in the instant claims as being the substance capable of providing a crystal that can penetrate the cell wall of an undesirable biological agent. Thus, the silica absorbents in the solid antimicrobial composition in the method taught by

Donovan et al. must also necessarily have the same capability recited in the instantly claimed invention.

It is further noted that the claimed method recites the use of a treatment substance which is open to containing any other ingredients in addition to a compound that is capable of providing a crystal, such as silicate, by virtue of the term "comprising." Thus, the composition containing glutaraldehyde in the method taught by Donovan et al. is not excluded by the instantly claimed invention, and the instantly claimed invention is anticipated for the reasons discussed above.

Moreover, given the teachings of Donovan et al., one of ordinary skill in the art could readily envisage providing the compounds for the treating of the aqueous biological spill before or after identifying the environment, such as the area in which the aqueous spill occurs, thus meeting the limitations of the instant claims 15-16.

Donovan et al. also teaches the use of the same compound, e.g., sodium metasilicate. Thus, the compounds in the compositions of Donovan et al. must also be within the definition of the "soluble compound" as claimed in the instant claims 6 and 17-18.

10. Claims 1, 3, 7, 9-10, 13, and 15-16 rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al. (US 6,455,751 B1).

Hoffman et al. teaches a method of decontaminating an area or items exposed to toxic chemical and biological agents such as anthrax comprising

applying a gel comprising a liquid oxidizer solution and gelling agent directly to the contaminated area (see abstract, column 2, lines 25-31, and claim 19): The gelling agent is in the form of colloids (fine-grained particles in suspension is a carrier liquid) and added to aqueous oxidizer solutions to form a viscous colloidal gel (see column 3, lines 31-34) meeting the limitation of the instant claims 9-10, 13, and 14 wherein the treatment substance comprises a slurry. Suitable colloidal materials include alumino-silicate minerals meeting the limitation of the instant claim 3 requiring the treatment substance to comprise a silicate (see column 3, lines 55-60).

Hoffman et al. further teaches that the gel can be prepared at the site of decontamination immediately before application to the contaminated area and applied by a sprayer (see abstract and column 8, lines 29-30) meeting the limitations of the instant claims 10 and 15. However, given the teachings of Hoffman et al., one of ordinary skill in the art could readily envisage providing the gel components before or after taking action to identify the contaminated environment to achieve the same expected results. Thus, the limitations of the instant claim 16 are also met.

Hoffman et al. is silent with respect to the capability of the treatment substance gel to provide a crystal that can penetrate the cell wall of the undesirable biological agent. However, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 201 USPQ 658

(CCPA 1979). Furthermore, the method taught by Hoffman et al. has the requisite environment, the method steps, and the treatment substance containing a silicate of the instantly claimed invention, wherein the undesirable biological are taught to be killed or neutralized.

11. Claims 1, 3, 6-9, 12-17, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nirschl et al. (US 3,915,882).

Claims 1, 3, 7, 9, and 12-13 and 15-17 are described above. Claims 6 and 8 specify that the treatment substance comprises a soap and sodium surfactant salt respectively. Claim 14 requires the slurry to be above ambient temperature during the application process. Claim 21 further requires the soluble compound of claim 17 to comprise of sodium sulfate.

Nirschl et al. teaches granular laundering compositions comprising a curd-dispersant-containing soap-based granule with smectite-type clay attached to the surface of the granule (see abstract). In a specific example, a soap-based laundry granule composition is added to an aqueous laundering liquor at 100°F, wherein the composition rapidly dissolves and the clay is dispersed throughout the laundering liquor (forming a slurry), and fabrics laundered in said liquid are cleansed (see column 20, lines 16-23). Dirty laundry is an environment that is known to harbor bacteria and other undesirable biological agents. For example, a wet dirty towel or sweat-stained clothing will grow bacteria, as evidenced by strong odors. Thus, the limitations of the instant claims 1, 6, 9, and 12-16 are met. As stated above, one of ordinary skill in the art could readily envisage

providing the treatment substance before or after taking action to identify the environment to be treated as claimed in the instant claims 15-16.

Nirschl et al. is silent with respect to the capability of the laundry granule treatment substance to provide a crystal that can penetrate the cell wall of the undesirable biological agent. However, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Furthermore, the method taught by Nirschl et al. has the requisite environment, the method steps, and the treatment substance containing the soap, etc. of the instantly claimed invention, wherein the environment (laundry) is cleansed.

Nirschl et al. further teaches that the granule is comprised of a curd-dispersant and a water-soluble soap component. The soap components include alkali metal soaps such as sodium soaps (see column 5, lines 50-55 and Example I at column 19, lines 49-67), thus meeting the limitations of the instant claim 7. Nirschl et al. also teaches the presence of sodium silicate, the sodium salt of linear alkyl benzene sulfonate (sodium surfactant salt), and sodium sulfate in the laundry granule compositions (see Example I at column 19, lines 49-67), thus meeting the limitations of the instant claims 3, 8, 17, and 21.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. (US 6,455,751 B1).

Hoffman et al. is described above for 1, 3, 7, 9-10, 13, and 15-16.

Hoffman does not explicitly teach that the application of the treatment gel (slurry) comprises atomizing the gel as claimed in the instant claim 11.

However, Hoffman et al. does teach that the gels can be sprayed onto the contaminated environment, and atomizing is a form of spraying, wherein in the spray is a fine mist. Hoffman et al. also teaches designing the sprayers and nozzles to optimize the spraying of the gel (see column 9, lines 22-27).

Therefore, it would be obvious to one of ordinary skill in the art at the time of the

invention, to optimize the spraying level of the gel as suggested by Hoffman et al. in order to obtain a fine mist as claimed.

Hoffman et al. does not explicitly applying the gel when the water in said gel is above the ambient temperature of the environment as claimed in the instant claim 14. However, Hoffman et al. does teach that the thickening and gelation of the liquid systems depends on several parameters including concentration of gelling agent and temperature (see column 5, lines 38-42). Hoffman et al. also teaches that desirable properties in a treatment substance are that is in fluid enough to be quickly and easily applied, but viscous enough to adhere to angled or contoured surfaces (see column 2, lines 3-7).

It would be obvious to one of ordinary skill in the art at the time of the invention to apply the gel (slurry) taught by Hoffman et al. at a temperature above the ambient temperature of the environment when a higher concentration of gelling agent is used. One of ordinary skill in the art would be motivated to do so because it would decrease the viscosity of the gel during application of the environment, while still allowing for the application of thicker, more viscous gels.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. (US 6,455,751 B1) in view of Andersen et al. (US 4,284,599).

Hoffman et al. is described above for 1, 3, 7, 9-10, 13, and 15-16.

Hoffman et al. does not explicitly teach dipping a contaminated environment into the treatment gel (slurry) as claimed in the instant claim 12.

However, Hoffman et al. does teach that the gel can be applied to the recovery of equipment exposed to harmful agents (see column 2, lines 56-59).

Andersen et al. teaches a sterilization system comprising immersing (dipping) medical articles into a sterilizing solution where they are sterilized (see abstract and claim 1). In Example VI (at column 19, line 11), the sterilizing solution is used to decontaminated penicylinders infected with *Salmonella choleraesuis*, an undesirable biological agent.

It would be obvious to one of ordinary skill in the art at the time of the invention, that the treatment gel taught by Hoffman et al. can be used as a dipping bath for an environment that has been contaminated with an undesirable biological agent as taught by Andersen et al. One of ordinary skill in the art would be motivated to do so when the environment is an article, such as a piece of medical equipment, for the ease of application.

14. Claim 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nirschl et al. (US 3,915,882).

Nirschl et al. is described above for claims 1, 3, 6-9, 12-17, and 21.

Nirschl et al. does not explicitly teach a laundry granule composition comprising (treatment substance) wherein the soluble portion comprises sodium carbonate and a silicate, as claimed in the instant claim 23. However, Nirschl et al. teaches that alkaline builders such as sodium carbonate or sodium tripolyphosphate may also be present in the composition (see column 13, lines 30-34). Furthermore, in Examples III and IV, Nirschl et al. teaches compositions

where sodium silicate and sodium tripolyphosphate are present (see column 21). Therefore, it would be obvious to one of ordinary skill in the art at the time of the inventions to substitute sodium carbonate for sodium tripolyphosphate in the compositions taught by Nirschl et al. because Nirschl teaches that both compounds are acceptable alkaline builders.

Nirschl et al. does not explicitly teach the claimed composition in claims 24-25. Claim 24 requires the soluble compound of claim 17 to comprise (a) 5% to 90% by weight sodium silicate; (b) 5 to 90% by weight sodium carbonate; and 0.1 to 20% sodium sulfate. Claim 25 further limits the soluble compound of claim 17 to comprising (a) 40 to 75% by weight sodium silicate; 20 to 40% by sodium carbonate; and 2 to 5% by weight sodium sulfate.

However, Nirschl et al. teaches compositions in Examples I-IV that comprise 5.5 to 8.9% by weight sodium silicate, and in Examples I-II, 11.9% by weight sodium sulfate (see column 19, line 49 to column 21, line 54). Nirschl et al. further teaches that the alkaline builder (sodium carbonate is typically present in 1 to 30% by weight (see column 13, lines 30-34). The weight percentages for the components taught by Nirschl et al. significantly overlap with the claimed weight percentages for components in the instant claim 24.

Nirschl et al. fails to teach the higher concentration of sodium silicate and lower concentration of sodium sulfate as claimed in the instant claim 25.

However, absence a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the amounts of sodium silicate and sodium sulfate in the compositions taught by

Nirschl et al. by routine experimentation. Nirschl et al. teaches that sodium silicate is a pH adjusting agent and sodium sulfate is a filler material (see column 13, lines 35-41). The optimization of the components present in the composition is addressed in *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Accordingly, absence of a showing of unexpected results, discovery of an optimum variable in a known invention is obvious when the parameter optimized is recognized as a result-effective variable. Therefore, the optimization of the sodium silicate and sodium sulfate of the instant invention, to adjust the pH and to adjust the amount of filler material, is well within the level of ordinary skill in the art, and a matter of routine experimentation.

15. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nirschl et al. (US 3,915,882) as applied to claims 1, 3, 6-9, 12-17, and 21 in view of Falou et al. (US 5,160,654).

Nirschl et al. is described above for claims 1, 3, 6-9, 12-17, 21 and 23-25.

Nirschl et al. does not teach compositions where the soluble component comprises magnesium sulfate.

Falou et al. teaches laundry treatment products wherein the product composition may contain an inorganic salt as a filler (see abstract and column 6, lines 63). Sodium sulfate and magnesium sulfate are listed as acceptable filler materials.

It has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. V. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would be obvious to one of ordinary skill in the art to substitute the sodium sulfate in the composition taught by Nirschl et al. with magnesium sulfate as taught by Falou et al. One of ordinary skill in the art would have a reasonable expectation of deriving the same effect as sodium sulfate, because sodium sulfate and magnesium sulfate are both inorganic salts, and used for the same purpose in laundry compositions as filler materials.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nirschl et al. (US 3,915,882) as applied to claims 1, 3, 6-9, 12-17, and 21 in view of Harris et al. (US 4,321,157).

Nirschl et al. is described above for claims 1, 3, 6-9, 12-17, 21 and 23-25.

Nirschl et al. does not explicitly teach using an acid in the composition to reduce the pH of the laundry slurry created when the granule is mixed with the laundering liquor as claimed in the instant claim 26. However, Nirschl et al. does teach that pH adjusting agents may optionally be present in the granule composition (see column 13, lines 35-44).

Harris et al. teaches granular laundry compositions comprising particulate mixtures of water-insoluble silicate, an organic peroxy acid bleach precursor, and an alkoxyated nonionic surfactant. Harris et al. further teaches that a pH

regulating may be added to the composition to provide the necessary pH control, and that regulating agents include organic acids such as succinic acid or citric acid (see column 16, lines 28-56).

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to use an acid pH regulating agent as taught by Harris et al. in the composition of Nirschl et al. One of ordinary skill in the art would be motivated to use acid pH regulating agents to provide pH control and achieve the desired pH.

Conclusion

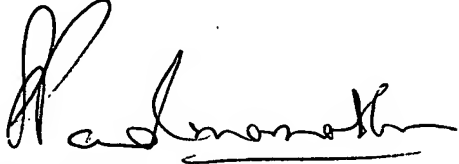
No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571) 270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK



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